Citation:

Larson EL, Lin SX, Gomez-Pichardo C, Della-Latta P. Effect of antibacterial home cleaning and handwashing products on infectious disease symptoms: A randomized, double-blind trial. *Ann Intern Med.* 2004 Mar 2; 140(5): 321-329.

PubMed ID: 14996673

Study Design:

Randomized controlled trial.

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effect of antibacterial cleaning and hand washing products on the occurrence of infectious disease symptoms in households.

Inclusion Criteria:

- Residents of an inner-city neighborhood in northern Manhattan
- Household unit with three or more persons
- At least one member of the household was preschool-aged child
- Had access to a telephone
- Household members had to speak English or Spanish.

Exclusion Criteria:

Excluded if not included above.

Description of Study Protocol:

Recruitment

Recruited by word of mouth, referral, English and Spanish flyers in the community. Participants were recruited by an experienced, trainer interviewer who resided in the community and was a native Spanish speaker.

Design

Randomized controlled trial.

Blinding Used

Double-blinded (subjects and researchers).

Intervention

- Households were randomly assigned to use either antibacterial or non-antibacterial products for general cleaning, laundry and hand washing
- Households in the intervention group were given liquid kitchen spray and all purpose hard-surface cleaner with quaternary ammonium compound, liquid hand washing soap with triclosan and laundry detergent with oxygenated bleach
- Households in the control group were given liquid kitchen spray and all purpose hard-surface cleaner without quaternary ammonium compound, liquid hand washing soap without triclosan and laundry detergent without oxygenated bleach
- Both groups were given liquid dishwashing detergent and bar soap without antibacterial ingredients.

Statistical Analysis

- Power analysis completed
- Used intention-to-treat analysis
- Student T-test to compare the characteristics of the antibacterial and non-antibacterial groups for each hygienic practice and demographic variable, and health status of household members at baseline
- Logistic regression to calculate relative risks and 95% CI for each symptom, using generalized estimating equations approach
- Poisson regression to estimate the number of different symptoms reported by each household, and the incidence density ratio comparing the number of symptoms in the two treatment groups
- Chi-square analyses to examine the effect of the intervention among household members with particular health risks.

Data Collection Summary:

Timing of Measurements

Baseline, weekly telephone calls, monthly home visits and quarterly interviews for 48 weeks.

Dependent Variables

Presence of at least one infectious disease symptom within the household for each one-month period. Symptoms of interest included vomiting, diarrhea, fever, sore throat, cough, runny nose, skin infection or conjunctivitis (pinkeye). This variable was self-reported and assessed during weekly telephone calls. Follow-up confirmation was done for the first 100 reports.

Independent Variables

- Households were randomly assigned to use either antibacterial or non-antibacterial products for general cleaning, laundry and hand washing
- Adherence to treatment was assessed during monthly home visits.

Control Variables

- Cleaning and hygiene practices

- Number of children younger than six years of age
- Number of people who rated their health as poor or fair or who had chronic conditions
- Number of people who spent 40 or more hours outside the household per week
- Size of the household
- All assessed by quarterly interviews using Home Hygiene Assessment Form.

Description of Actual Data Sample:

- *Initial N:* 238 households (120 intervention, 118 control) with 1,178 household members (592 intervention, 586 control)
- *Attrition (final N):* 224 households (94% completion, 116 intervention, 108 control). Intention-to-treat analysis was conducted so analyses were based on the initial N.
- *Age:*
  - 51.9% of enrolled household members were 19 years or younger
  - 28.6% 20 to 35 years
  - 11.8% 36 to 45 years
  - 6% 46 to 60 years
  - 1.7% older than 60 years
  - There were no differences in age distribution between intervention and control groups
- *Ethnicity:*
  - 98.3% Hispanic
  - 0.9% African American
  - 0.4% non-Hispanic White
  - 0.3% other
  - There were no differences in ethnicity distribution between intervention and control groups
- *Other relevant demographics:*
  - 53.2% born outside of the US
  - 12.1% with chronic condition
  - 54.4% of adults employed in child care, homemaker, food services or health care
  - There were no differences in the distribution of these variables between intervention and control groups. Most households resided in multiple-unit buildings (90.8% in intervention, 94.1% in control).
- *Location:* Manhattan, New York.

Summary of Results:

Key Findings

- Rates of any infectious disease symptoms did not differ between intervention and control groups. The unadjusted and adjusted relative risks for any symptoms were not significant.
- Providing a bundle of antibacterial home cleaning and hand washing products, including liquid triclosan-containing soap, did not reduce the risk of respiratory and viral GI infections
- The incident density ratio comparing the number of infectious disease symptoms in the two treatment groups was 0.96 (95% CI: 0.82 to 1.12, P=0.19), with cumulative incidence of 38% in intervention group and 32.1% in control group.

Other Findings

- Symptoms were primarily respiratory; during 26.2% (717 of 2,736) of household months, 23.3% (640 of 2,737) of household months and 10.2% (278 of 2,737) of household months, one or more members of the household had a runny nose, cough or sore throat, respectively
- Fever was present during 11% (301 of 2,737) of household months, vomiting was present in 2.2% (61 of 2,737), diarrhea was present in 2.5% (69 of 2,737) and boils or conjunctivitis were present in 0.77% (21 of 2,737)
- Among household members self-reported with chronic disease or poor health, individuals in the intervention group were significantly more likely to have fever, runny nose and cough
- The rates of any infectious disease symptoms did not differ by children's age above or below six (P>0.2), children's attendance of daycare (P>0.2) or adults working outside the home for more or less than 40 hours (P>0.10)
- In the majority of households (58.8%), one person prepared 11 or more meals per week at home. Automatic dishwashers were used in 2.2% of households. A commercial or shared laundry facility was used in 34.5% of households.

Author Conclusion:

The risk for viral infectious diseases symptoms was not reduced by antibacterial products in households that included essentially healthy persons. This does not preclude the potential contribution of these products to reducing symptoms of bacterial diseases in the home.

Reviewer Comments:

- *In the investigation effect modification by poor health or chronic disease, children who were five years of age or younger or were attending daycare, and adults working outside the household for 40 or more hours per week (among household members, not at the household level), it was unclear if multiple testing adjustment was used*
- *No analyses was done to examine if outcome occurrence differed between the two treatment groups as time changes*
- *Authors noted the following limitations:*
  - *Conducted in a crowded urban setting, may not be generalizable to suburban families with smaller family sizes*
  - *No guarantee that the participants actually used the products as directed*
  - *Weekly telephone calls and monthly visits to households as well as the provision of free products probably increased product use, potentially biasing the study toward having fewer infectious disease symptoms in both groups because of generally increased levels of cleanliness.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes

3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A

3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A

6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes

10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes